SECTION 5 **510K SUMMARY**

510(k) Summary for Flexiva™ SF Side-Firing Single-Use Laser Fiber

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

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or

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C. Device Name

Trade name: Flexiva™ SF Side-Firing Single-Use Laser Fiber
Common usual/name: Laser Instrument, Surgical, Powered
Classification: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4810, Class II

D. Predicate Device(s)

Trade name: DuoTome™ SideLite™ Fiber (cleared under K011703 as Lumenis delivery devices)
Common usual/name: Laser Instrument, Surgical, Powered
Classification: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4810, Class II
Premarket Notification: Lumenis, K011703

and

Trade name: Flexiva™ High Power Single-Use Laser Fiber (cleared under K100078 as Modified Straight Fire Laser Fiber)
Common usual/name: Laser Instrument, Surgical, Powered
Classification: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4810, Class II
Premarket Notification: Boston Scientific, K100078

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E. Device Description

The Flexiva SF Side-Firing Single-Use Laser Fibers (Flexiva SF) are fiber optic laser energy delivery devices consisting of an SMA-905 connector and a coated silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The Flexiva SF fibers are equipped with a metal cap with circumferential solid black line guides, an adjustable hand piece and rigid tubing. The laser aperture is located near the tip of the metal cap. Laser energy is delivered at an approximately 70° angle to tissue from the tip of the fiber. The line guides assist with correct positioning of the fiber tip within the endoscope. The adjustable hand piece enables manipulation of the laser fiber tip at the treatment site. The rigid tubing aids in control of the fiber tip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems.

F. Intended Use

The Flexiva SF fiber is designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that has been cleared for surgical use.

G. Technological Characteristics

The Flexiva SF fiber has the same technological characteristics and fundamental design as the predicate devices. The proposed Flexiva SF fiber is available in a single configuration.

H. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the Flexiva SF fiber is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance characteristics. The Flexiva SF fiber is as safe and effective as the predicate devices.

I. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 and T=6 months accelerated aging in support of the proposed laser device. The following testing was completed to evaluate the effects of the design change:

- Operating Life
- Hand-Piece Retention Strength
- Initial Fiber Power Transmission
- Fiber Power Transmission
- Fiber Control

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- Protective Cap Retention Strength
- Fiber Length
- Distal Fiber Max OD
- Aiming Beam
- Connector Temperature/Durability
- Connector Tensile
- Seal Integrity
- Seal Strength

The results of the performance testing demonstrate that the Flexiva SF fiber is considered safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2014

Boston Scientific Corporation
Ms. Jeanne O'Toole
Senior Specialist, Regulatory Affairs
100 Boston Scientific Way
Marlborough, Massachusetts 01756

Re: K140503
Trade/Device Name: Flexiva™ SF Side-Firing Single-Use Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 31, 2014
Received: April 1, 2014

Dear Ms. O'Toole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140503

Device Name
Flexiva™ SF Side-Firing Single-Use Laser Fiber

Indications for Use *(Describe)*
The Flexiva SF Side-Firing Single-Use Laser Fiber is designed for use with Ho:YAG and Nd:YAG lasers for indications that are cleared for these laser systems, including, but not limited to endoscopic, laparoscopic, and open surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection, incision of soft and cartilaginous tissue, and fragmentation of urinary and biliary calculi (Ho:YAG wavelength only). The fiber is designed for use with a standard SMA-905 connector that has been cleared for surgical use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
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For BSA
PSC Publishing Services (301) 443-6740 EF